

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

DMB

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[Docket No. 98N-0170]

Medical Devices; Medical Device Reporting Regulations; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing Medical Device Reporting (MDR) requirements. When the final regulation was last amended, the regulation published with some errors and omissions that, if uncorrected, may prove to be misleading. This document corrects those errors.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Susan E. Bounds, Center for Devices and Radiological Health (HFZ-500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-2735.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 26, 2000 (65 FR 4112), FDA published a final rule (the January 2000 rule) that amended its MDR regulations governing reporting by manufacturers, importers, distributors, and user facilities of adverse events related to medical devices. These amendments were made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) under the Food and Drug Administration Modernization Act of 1997 (FDAMA). These regulations became effective March 27, 2000. Under certain provisions of FDAMA, reporting

requirements for distributors were eliminated, but reporting requirements for importers, and requirements for distributors to keep records concerning adverse device events and make them available to FDA upon request continue to apply. To accommodate these changes, part 804 (21 CFR part 804) was removed and language was integrated into part 803 (21 CFR part 803) that reflected the retention of importer reporting requirements and recordkeeping requirements for distributors. Another change made by the January 2000 rule revised procedures to require annual, rather than semiannual, summary reporting by user facilities, and eliminated reporting certification requirements. As a result of these substantive amendments, many nonsubstantive changes were made to the organization of provisions in part 803. During preparation of the final rule for publication, however, a number of typographical and editorial errors occurred. In the subsequent months, FDA discovered other errors. The purpose of these amendments is to correct the errors identified in part 803. This document is published as a final rule with the effective date shown above. FDA has determined that this final rule has no substantive impact on the public. FDA, therefore, for good cause, finds under 5 U.S.C.553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

II. Need for Amendments

A. Incorporation of Importer Reporting Requirements Into Part 803

Section 213 of FDAMA eliminated reporting requirements for distributors previously found at part 804. At the same time, reporting requirements for importers were retained and those previously referenced in part 804 were incorporated in part 803. Accordingly, the word “distributor” was removed from applicable paragraphs and the word “importer” was integrated into the text. During preparation of the final rule amending the regulations to incorporate importer requirements, however, the word “importer” was not properly integrated into §§ 803.10, 803.20, 803.50, and 803.52. FDA is amending the regulations to correct this error.

B. Elimination of Reporting Certification and Modification of Semi-Annual Reporting

Section 213(a)(2) of FDAMA revoked section 519(d) of the act (21 U.S.C. 360i(d)) resulting in the elimination of certification requirements. Section 213(c)(1)(A) revised section 519(b)(1)(C) of the act to require annual, rather than semiannual, summary reporting by user facilities. During preparation of the final rule, however, an editorial error led to the omission in certain paragraphs of amended text that was written to remove references to certification requirements and change the word “semiannual” to “annual.” Sections 803.10, 803.17, and 803.58 contained these errors. FDA is amending the regulations to correct these errors.

C. Organization of Paragraphs

The integration of importer reporting requirements and the removal of certification references required substantial reorganization of part 803. This reorganization included the need to redesignate certain paragraphs and correct references to those paragraphs throughout the text.

1. Definition of Device User Facility, MDR Reportable Event (or reportable event), and Work Day (§ 803.3(f), (r)(2)(ii), and (ee))

Modifications to § 803.3 require that paragraphs (m) through (ee) be redesignated as paragraphs (n) through (ff) to address the following:

- At paragraph (f), the definition of a “device user facility” states that a “physician’s office” is later defined in paragraph “(w)” of this section. In fact, the definition of “physician’s office” is found later at paragraph “(x)” of this section.
- A further error occurred when redesignating the definition of an “MDR reportable event (or reportable event)” as paragraph (r)(2)(ii). In this instance, the words “or contribute” were inadvertently omitted after the words “would be likely to cause,” in the definition text.
- Finally, § 803.3 contains two paragraphs “(ee)” because the definition of “work day” was not redesignated as paragraph “(ff).”

FDA is amending the regulations to correct these errors.

2. General Description of Reports Required From User Facilities, Importers, and Manufacturers (§ 803.10(b))

Previously, § 803.10(b) was reserved. As amended by the January 2000 rule, § 803.10(b) was revised to include reporting requirements for importers. During preparation of the January 2000 rule, the amended text incorporated in this section was not organized in the same manner as § 803.10(a) and (c). FDA is amending the regulations to correct this error.

3. Foreign Manufacturers (§ 803.58(b)(4), (b)(5), and (b)(6))

The elimination of certification requirements by manufacturers resulted in the removal of § 803.58(b)(3); therefore, paragraphs (b)(4), (b)(5), and (b)(6) were to be redesignated accordingly. FDA is amending the regulations to correct this error.

4. Exemptions, Variances, and Alternative Reporting Requirements (§ 803.19)

Independent of the errors in part 803 that resulted from the January 2000 rule, FDA discovered an obsolete reference in § 803.19(a)(2). In this instance, the text of § 803.19(a)(2) references part 813, which was removed by a final rule published in the **Federal Register** on January 29, 1997 (62 FR 4164). FDA is amending the regulations to correct this error.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and

benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that this final rule will not have a significant negative economic impact on a substantial number of small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any 1 year (adjusted annually for inflation). The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million.

V. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no additional collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 803 is amended as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

2. Section 803.3 is amended by revising paragraphs (f) and (r)(2)(ii) and by redesignating the second paragraph (ee) as paragraph (ff) to read as follows:

§ 803.3 Definitions.

* * * * *

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in paragraphs (b), (l), (t), (u), and (v), respectively, of this section, which is not a “physician’s office,” as defined in paragraph (x) of this section. School nurse offices and employee health units are not device user facilities.

* * * * *

(r) * * *

(2) * * *

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

* * * * *

3. Section 803.10 is amended by revising paragraph (b) and by removing paragraph (c)(5) to read as follows:

§ 803.10 General description of reports required from user facilities, importers, and manufacturers.

* * * * *

(b) *Device importers*. Importers must submit the following reports, which are described more fully in subpart D of this part.

(1) Importers must submit MDR reports of individual adverse events within 30 days after the importer becomes aware of an MDR reportable event as described in §§ 803.40 and 803.42.

(i) Importers must submit reports of device-related deaths or serious injuries to FDA and to the manufacturer.

(ii) Importers must submit reports of malfunctions to the manufacturer.

(2) [Reserved]

* * * *

4. Section 803.17 is amended by revising paragraph (b)(3) to read as follows:

§ 803.17 Written MDR procedures.

* * * *

(b) * * *

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

* * * *

5. Section 803.19 is amended by revising paragraph (a)(2) to read as follows:

§ 803.19 Exemptions, variances, and alternative reporting requirements.

(a) * * *

(2) An individual who manufactures devices intended for use in humans solely for such person's use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the investigational device exemption regulations, part 812 of this chapter, which require reporting of all adverse device effects.

* * * *

6. Section 803.20 is amended by revising the introductory text of paragraph (a), and paragraphs (a)(2) and (c)(1) to read as follows:

§ 803.20 How to report.

(a) *Description of form.* There are two versions of the MEDWATCH form for individual reports of adverse events. FDA Form 3500 is available for use by health professionals and consumers for the submission of voluntary reports regarding FDA-regulated products. FDA Form 3500A is the mandatory reporting form to be used for submitting reports by user facilities, importers, and manufacturers of FDA-regulated products. The form has some sections that must be completed by all reporters and other sections that must be completed only by the user facility, importer, or manufacturer.

* * * * *

(2) The back part of the form contains sections to be completed by user facilities, importers, and manufacturers. User facilities and importers must complete section F; device manufacturers must complete sections G and H. Manufacturers are not required to recopy information submitted to them on a Form 3500A unless the information is being copied onto an electronic medium. If the manufacturer corrects or supplies information missing from the other reporter's 3500A form, it should attach a copy of that form to the manufacturer's report form. If the information from the other reporter's 3500A form is complete and correct, the manufacturer can fill in the remaining information on the same form.

* * * * *

(c) *Information that reasonably suggests a reportable event occurred.* (1) Information that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event (i.e., death, serious injury, and, for manufacturers and importers, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur) includes any information, such as professional, scientific or medical facts and observations or

opinions, that would reasonably suggest that a device has caused or may have caused or contributed to a reportable event.

* * * *

7. Section 803.50 is amended by revising paragraphs (b)(1)(i) and (b)(2) to read as follows:

§ 803.50 Individual adverse event reports; manufacturers.

* * * *

(b) * * *

(1) * * *

(i) Any information that can be obtained by contacting a user facility, importer, or other initial reporter;

* * * *

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under § 803.56.

8. Section 803.52 is amended by revising paragraphs (d)(1), (f)(11)(i), and (f)(11)(ii) to read as follows:

§ 803.52 Individual adverse event report data elements.

* * * *

(d) * * *

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or importer;

* * * *

(f) * * *

(11) * * *

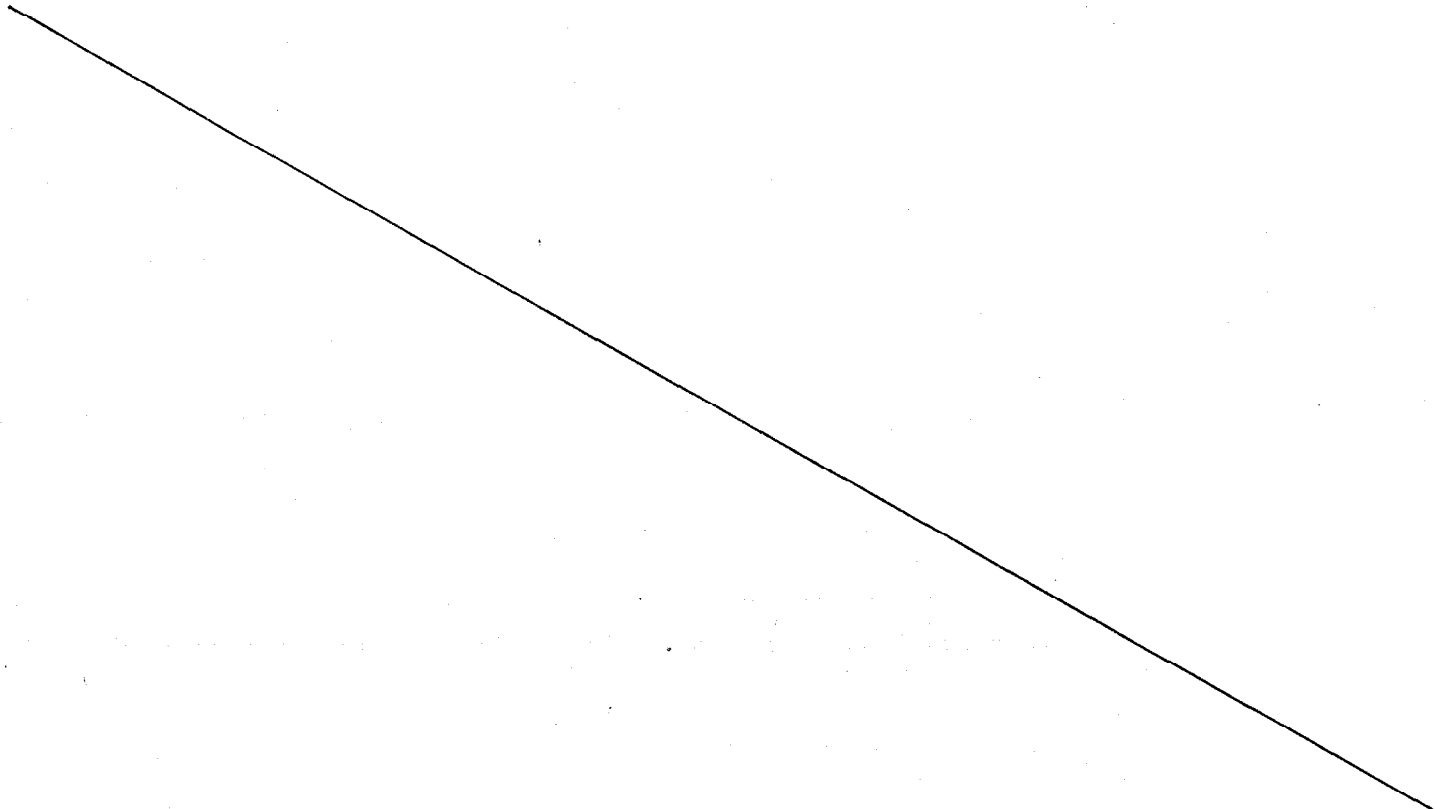
(i) Any information missing on the user facility report or importer report, including missing event codes, or information corrected on such forms after manufacturer verification;

(ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), a statement of whether the type of event represented by the code is addressed in the device labeling; and

* * * *

§ 803.58 [Amended]

9. Section 803.58 *Foreign manufacturers* is amended by removing paragraph (b)(3) and by redesignating paragraphs (b)(4), (b)(5), and (b)(6) as paragraphs (b)(3), (b)(4), and (b)(5), respectively.



Dated: 4/18/01
April 18, 2001.

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CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



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